

REMARKS

I. Status of the Claims

The examiner maintained rejection of claims 53, 55 and 57 under 35 U.S.C. §103(a) over Cham et al. (Australian Patent No. 57853/80). The status of claim 79 is shown as rejected at page 2 of the office action, but no basis for the rejection is set forth.

Claim 53 is amended herein to embrace only the subject matter of previous claim 55. Claim 55 is accordingly cancelled to remove redundancy. The amendment to claim 53 also required cancellation of either claim 57 or 79 to also remove redundancy; and as such claim 79 is also cancelled herein.

Amendment to the claims is made without prejudice to the applicant's right to pursue claims of the same or similar scope in a duly filed continuing application. Amendments are made herein only for purposes of expediting prosecution. The amendments include no new matter.

II. The rejection under 35 U.S.C. § 103 (a) over Cham et al. must be withdrawn.

The examiner maintained rejection of claims 53, 55 and 57 under 35 U.S.C. § 103 (a) over Cham et al. (Australian Patent No. 57853/80, hereinafter "Cham") for reasons of record.

Applicant's previously submitted that the Cham disclosure is directed to a composition comprising 33% solasonine, 33% solamargine and a third component which the instant claims expressly preclude. Moreover, the applicant submitted a declaration showing comparative experimental results using the instantly claimed solamargine and solasonine composition and the BEC composition disclosed in Cham. In response, the examiner asserted that these arguments were not persuasive because claims 53, 55 and 57 "are not limited to the composition tested." [Office action at page 3] The examiner attempted to underscore this point by asserting that a composition "consisting essentially of tomatine and

276-aminofurostane" has not been shown to be more effective than the Cham BEC composition. [Id.] Further, the examiner continued with the following additional comments:

- With respect to claim 79, said claim is directed to treatment of psoriasis.
- Further said claim is not limited to any mode of administration and therefore encompasses topical administration, intravenous administration and oral administration.
- Further it is not clear from the declaration if the amounts of the solamargine and solasonime present in BEC composition tested where [*sic*] the same in the composition containing just solamargine and solasonime.
- Thus, the significant of the results presented in the declaration cannot be ascertained.

The applicant respectfully disagrees. The rejection is flawed for a number of reasons and as such, must be withdrawn.

First, with respect to the examiner's assertion that the claims are not limited to the solamargine and solasonime composition tested in the previously submitted declaration, it is noted that the subject matter of previous claims 55 and 79, now the subject matter of claim 53 and 57, was in fact limited to solamargine and solasonime compositions. Accordingly, the examiner's first argument with respect to those claims is wholly inaccurate.

Second, the examiner's assertion that it is not clear from the declaration if the amounts of solamargine and solasonime present in BEC tested were the same in the composition containing just solamargine and solasonime represents a misunderstanding of the experimental data in the declaration. In paragraph 10 of the declaration, lethal doses (LD₅₀) of total glycoalkyloid in µg/ml of various compositions is presented. These data show that for BEC, 4.4 µg/ml total glycoalkyloids killed 50% of the tested cells, while 1.47 µg/ml total glykoalkyloids in a 1:1 mixture of solamargine and solasonime achieved the same result. These results are a direct comparison of the amounts of glycoalkyloids in each composition required to achieve a specific result. Showing that it took 4.4 µg/ml total glycoalkyloids in BEC to achieve a result that required only 1.47 µg/ml total glycoalkyloids in a solasonine and solamargine compositions necessarily means that 1.47 µg/ml total glycoalkyloids in a BEC composition could not achieved what the claimed composition did. In other words, the same amounts of glycoalkyloids were in fact tested.

Third, the examiner has apparently asserted that different routes of administration must be compared in the declaration in order to show the heightened effect of the claimed composition compared to Cham's BEC composition, and if true, this position is without merit. The data expressly show that the total glycoalkaloids in the claimed composition is more effective at killing cells than the total glycoalkaloids in Cham's BEC composition in the method tested. MPEP 716 states,

It is the responsibility of the primary examiner to personally review and decide whether affidavits or declarations submitted under 37 CFR 1.132 for the purpose of traversing grounds of rejection are responsive to the rejection and present sufficient facts to overcome the rejection.

This same section also dictates how the examiner must respond if for some reason it is believed that declaration evidence is insufficient. Here, in attempting to explain why the submitted declaration is somehow insufficient, the examiner appears to be requiring the applicant to demonstrate unexpected and superior results over the full scope of the claim, i.e., by every route of administration embraced by the claim. This requirement, however, sets a threshold for evidence that is contrary to what is required. MPEP 2145 states,

When considering whether proffered evidence is commensurate in scope with the claimed invention, Office personnel should not require the applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition. See, e.g., *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a prima facie case of obviousness. *Id.*

Clearly then, the examiner's assertion that the declaration is insufficient for failure to demonstrate superior results from multiple routes of administration is inappropriate.

Thus, in view of fact that the examiner mischaracterized subject matter of rejected claims, misunderstood the substance of application's declaration evidence, and dismissed the declaration evidence for inappropriate reason, the applicant submit that the rejection of claims for asserted obviousness must be withdrawn.

III. Conclusion

For the foregoing reasons, applicants submit that all claims are in condition for allowance and request expedited notification of the same.

If the examiner believes that a telephone conversation would expedite allowance of the claims, she is invited to contact the undersigned at the number below.

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Respectfully submitted,

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